## THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

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Before STONER, <u>Chief Administrative Patent Judge</u>, WINTERS and WILLIAM F. SMITH, <u>Administrative Patent Judges</u>.

WILLIAM F. SMITH, Administrative Patent Judge.

## **DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 2 through 6 and 9 through 13, all the claims remaining in the application.

<sup>&</sup>lt;sup>1</sup> Application for patent filed October 7, 1991.

Application 07/752,639

Claims 6, 11 and 13 are illustrative of the subject matter on appeal and read as follows:

6. A peptide consisting of at least one antigenic structure for HTLV-I or HTLV-II selected from the following sequences:

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HTLV-I gag 130-197 PVMHPHGAPPNHRPWQMKDLQAIKQEVSQAAPGSPQFMQTIRLAVQQFDPTAKDLQDLLQYLCSSLVA
HTLV-II gag 137-214 PILHPPGAPSAHRPWQMKDLQAIKQEVSSSALGSPQFMQTLRLAVQQFDPTAKDLQDLLQYLCSSLVV
HTLV-I -gag 298-349 LRSLAYSNANKECQKLLQARGHTNSPLGDMLRACQTWTPKDKTKVLVVQPKK
HTLV-II gag 305-356 LRSLAYSNANKECQKILQARGHTNSPLGEMLRTCQAWTPKDKTKVLVVQPRR
HTLV-I gag 4-20 IFSRSASPIPRPPRGLA
HTLV-II gag 4-20 IHGLSPTPIPKAPRGLS
HTLV-I gag 111-130 PDSDPQIPPPYVEPTAPQVL
HTLV-II gag 117-136 PSPEAHVPPPYVEPTTTQCP
HTLV-I gag 265-285 SILQGLEEPYHAFVERLNIAL
HTLV-I gag 302-320 LAYSNANKECQKLLQARGH
HTLV-I gag 323-341 SPLGDMLRACQTWTPKDKT
HTLV-1 gag 337-355 PKDKTKVLVVQPKKPPPNQ
HTLV-II gag 343-361 PKDKTKVLVVQPRRPPPTQ
HTLV-1 gag 378-399 PCPLCQDPTHWKRDCPRLKPT
HTLV-I gag 392-411 DCPRLKPTIPEPEPEEDALL
HTLV-II gag 398-416 DCPQLKPPQEEGEPLLLDL
HTLV-I env 190-213 LLPHSNLDHILEPSIPWKSKLLTL
HTLV-II env 186-209 LVHDSDLEHVLTPSTSWTTKILKF
HTLV-I env 290-312 HNSLILPPFSLSPVPTLGSRSRR
HTLV-I env 360-378 AIVKNHKNLLKIAQYAAQN
HTLV-I env 376-392 AGNRRGLDLLFWEGGGL
HTLV-I env 380-398 RGLDLLFWEQGGLCKALQE
HTLV-I env 465-488 RQLRHLPSRVRYPHYSLILPESSL
HTLV-II env 463-486 IQALPQRLQNRHNQYSLINPETML
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- 11. A method of differentiating in a test sample antibodies arising from HTLV-I infection and antibodies arising from HTLV-II infection comprising analyzing the test sample in at least four immunoassays that each employ
  - (I) at least one synthetic peptide from each of groups a) to d):
- a) a synthetic peptide comprising 17 to 68 amino acids and at least one antigenic structure, said peptide derived from the HTLV-I gag gene;
- b) a synthetic peptide comprising at least 17 amino acids and at least one antigenic structure, said peptide derived from the HTLV-II gag gene;
- c) a synthetic peptide comprising at least 17 amino acids and at least one antigenic structure, said peptide derived from the HTLV-I <u>env</u> gene;
- d) a synthetic peptide comprising at least 17 amino acids and at least one antigenic structure, said peptide derived from the HTLV-II env gene; and
- (ii) at least one pair of synthetic peptides derived from HTLV-I and HTLV-II gene sequences selected from each of the groups a) plus b), and c) plus d);

wherein each of said immunoassays employs a different synthetic peptide selected from groups a) to d).

- 13. An immunoassay kit for differentiating in a test sample antibodies arising from HTLV-I infection and antibodies arising from HTLV-II infection comprising one or more containers holding synthetic peptides for analyzing a test sample in at least four immunoassays, said synthetic peptides comprising at least one peptide selected from each of groups a) to d):
- a) a synthetic peptide comprising at least 17 amino acids and at least one antigenic structure, said peptide derived from the HTLV-I gag gene;
- b) a synthetic peptide comprising at least 17 amino acids and at least one antigenic structure, said peptide derived from the HTLV-II gag gene;
- c) a synthetic peptide comprising at least 17 amino acids and at least one antigenic structure, said peptide derived from the HTLV-I <u>env</u> gene; and

d) a synthetic peptide comprising at least 17 amino acids and at least one antigenic structure, said peptide derived from the HTLV-II <u>env</u> gene.

Claims 2 through 6 and 9 through 13 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon twelve documents which are listed on pages 2-4 of the Examiner's Answer (Paper No. 17, April 14, 1994). We reverse.

#### **DISCUSSION**

We first note that the claims on appeal have not been examined on the merits throughout their scope. This has happened as a result of a requirement to elect a species. See Sections 15-22 of the first Office action on the merits (Paper No. 7, December 17, 1992). While the record is unclear as to which peptides appellants elected in response to this requirement, the examiner states at page 11 of the Examiner's Answer that only four of the peptides involved in the present invention have been considered on the merits. These are the four peptides identified in claim 6 reproduced above as HTLV-I gag 111-130, HTLV-II gag 117-136, HTLV-I env 190-213, and HTLV-II env 186-209. Thus, in deciding this appeal, we pass judgment only on that aspect of the claimed invention which requires the presence or use of these four peptides.

By statute, this board serves as a board of review, not as a <u>de novo</u> examination tribunal. 35 U.S.C. 7(b) ("The [board] shall . . . review adverse decisions of examiners upon applications for patents . . . "). Here, the statement of the rejection under

35 U.S.C. §103 set forth on pages 5-9 of the Examiner's Answer is not susceptible to a meaningful review.

As indicated above, the examiner relies upon twelve documents as evidence of obviousness. In stating the rejection, the examiner briefly describes each of the twelve references in one or two sentences. Beginning at the bottom of page 7 and continuing to the top of page 9 of the Examiner's Answer, the examiner makes a series of conclusions concerning what would have been obvious to one of ordinary skill in the art. Lacking from this portion of the statement of the rejection is a reference to any individual claim on appeal. Also, lacking is an explanation of why the references provide the requisite teaching, suggestion or motivation<sup>2</sup> to one of ordinary skill in the art to combine their disclosures in the manner needed in order to arrive at the subject matter of any individual claim.

It is the examiner's initial burden to establish reasons of unpatentability. In re

Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Absent a

more fact based explanation by the examiner as to why the subject matter of any
individual claim on appeal would have been obvious to one of ordinary skill in the art,
we are constrained to reverse the rejection.

<sup>&</sup>lt;sup>2</sup> As stated in <u>Pro Mold & Tool Co. v. Great Lakes Plastics, Inc.</u>, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996) (citations omitted):

It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references.

## OTHER ISSUES

We note that the examiner attempts to explain why the subject matter of claim 6 would have been obvious to one of ordinary skill in the art on pages 11-12 of the examiner's answer. However, these statements are made in response to arguments by appellants and do not form part of the examiner's statement of the rejection. When appellants attempted to respond to this newly stated position in the Reply Brief (Paper No. 18, June 17, 1994), the examiner refused to enter that paper. See the communication issued by the examiner on July 20, 1994 (Paper No. 19).

Upon return of the application, we urge the examiner to take a step back and reassess the patentability of the claims pending in this application. It seems unlikely that twelve documents are needed to establish the obviousness of any single claim on appeal. This points to the fact that the examiner needs to consider the patentability of the claims pending in this application on an individual basis, not as a group which has occurred during the examination of this application. It may be that the examiner has substantive reasons why the four polypeptides set forth in claim 6 which have been examined on the merits are unpatentable under 35 U.S.C. § 103. If so, those reasons have not been set forth in this record in a cogent and proper manner.

If as a result of the examiner's review of the record it is determined that the subject matter of any claim pending would have been obvious to one of ordinary skill in the art under 35 U.S.C. § 103, we urge the examiner to formulate such a rejection using the model

set forth in MPEP § 706.02(j). Adherence to this model will result in a statement of a rejection to which appellants can make a meaningful response and, if needed, any subsequent appeal can be decided in a straightforward manner.

As a second separate matter, the present invention involves a number of peptides of which only four have been examined on the merits. As a result of our decision today, it appears that the examiner will have to examine the claims on appeal throughout their scope. In so doing, the examiner should ensure that the appropriate electronic data bases which allow for a search of peptide sequences are properly accessed.

The decision of the examiner is reversed.

### REVERSED

Bruce H. Stoner, Jr. Chief Administrative Patent Judge )	)
Sherman D. Winters Administrative Patent Judge	) ) ) BOARD OF PATENT ) APPEALS AND ) INTERFERENCES )
William F. Smith Administrative Patent Judge	) ) )

WFS/cam Joseph C. Sullivan Appeal No. 95-1390 Application 07/752,639

KANE, DALSIMER, SULLIVAN, KURUCZ, LEVY, EISELE & RICHARD 711 Third Avenue New York, NY 10017-4059